

REMARKS

The Examiner has objected to claim 8 under 37 CFR 1.75(c) as being of improper dependent form for failing to further limit the subject matter of a previous claim. This objection is respectfully traversed.

Applicant respectfully submits that the Examiner has misunderstood said claim (new claim 22) since it is not meant that the granules are in solid form but rather that the granules are comprised in a solid form. A solid form or solid shape is a generally used term in the pharmaceutical field to denote tablets and other sorts of solid galenic forms of pharmaceutical compositions.

It is thus respectfully submitted that claim 22 is in fact unobjectionable.

Previous claim 4 is also objected to by the Examiner under 37 CFR 1.75(c) as being of improper dependent form for failing to further limit the subject matter of a previous claim.

This objection is respectfully traversed.

The Applicant has drafted new claim 15 as an independent claim which thus obviates the objection.

Claims 1 to 5 and 7 to 9 are rejected under 35 USC 112, 2<sup>nd</sup> paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

This rejection is respectfully traversed.

The claims have been amended to remove all indications of preferable ranges. Dependent claims have been inserted where necessary for claiming a preferred range.

Claims 1 to 5 and 9 are rejected under 35 USC 112, 2<sup>nd</sup> paragraph as being indefinite in that it fails to point out what is included or excluded by the claim language.

This rejection is respectfully traversed.

The Applicant assumes that the Examiner is referring only to claim 9 since he has further indicated that "this claim is an omnibus type claim". Previous claim 9 has been deleted, thus obviating this rejection.

The Examiner indicates that the scope of claim 4 is indefinite but said claim has since been amended, thus obviating this rejection.

It is respectfully submitted that all claims are now in conformity with the requirements of 35 USC 112, 2<sup>nd</sup> paragraph and consequently the objection should be withdrawn.

Claim 10 is rejected under 35 USC 102(b) as being clearly anticipated by Saito et al. (US 5,618,562).

This rejection is respectfully traversed.

Previous claim 10 has been cancelled and the feature reciting co-spray-dried lactose and starch granules has been inserted into new independent claim 11.

New independent claim 11 (which corresponds to previous claim 1) has also been amended so as to include a lactose starch ratio between 90/10 and 25/75.

Thus, the lactose starch granules of the present invention contain at most 90 % of lactose. These granules are clearly novel over those described in Saito et al. since the granules of Saito et al. comprise 95 % by weight or more of lactose (see column 2 line 17 of Saito et al.).

It is thus respectfully submitted that the claim rejection under 35 USC 102(b) should be withdrawn.

Claims 1 to 10 are rejected under 35 USC 103(a) as being unpatentable over Saito et al.

This rejection is respectfully traversed.

As has already been mentioned above, a major difference between the granules of Saito et al. with respect to those of the present invention is that the Saito et al. granules must contain at least 95 % of lactose. On the contrary, the granules of the present invention must not contain more than 90 % of lactose. As is clearly indicated as page 5 lines 26 to 33 of the present specification, granules containing more than 90 % of lactose do not possess satisfactory disintegrating properties.

There is absolutely no indication in the Saito reference that it is necessary to have a content of lactose of less than 90 % in order to obtain satisfactory disintegration properties of tablets containing said granules as excipients. In fact, the Saito reference teaches completely away from the granules of the present invention since it requires that the granules contain 95 % by weight or more of lactose.


Furthermore, new process claim 19 and its dependent claims are also novel and unobvious over the Saito reference since said reference neither teaches nor suggests co-spray-drying the lactose with the starch, but rather suggests a method of granulation in a fluidized bed.

It is thus respectfully submitted that all claims are indeed unobvious over the cited Saito reference.

It is hence respectfully submitted that the claims of the present application are in proper form for allowance.

Respectfully submitted.

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